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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416

7590 10/22/2002
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Washington Harbour
3000 K Street N W
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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/22/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,870

Applicant(s)

BRENNAN ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-65 is/are pending in the application.
- 4a) Of the above claim(s) 14-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim Status

The amendment filed on July 29, 2002 has been acknowledged and entered.

Claims 1-13 were canceled. Claims 14-49 are non-elected. New claims 50-65 have been added and are pending.

Withdrawn Rejection(s)

Rejections under 35 USC 112, 2nd paragraph are withdrawn herein.

All rejections under 35 USC 102 in the previous office action are withdrawn herein.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-65 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The reversibly disrupting factor, i.e. thermal, urea, GdHCl, is a critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the

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invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention- the instant invention is directed to a carrier comprising a matrix of organic, inorganic, or organic and inorganic material and containing a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from the other.

The state of the prior art- the prior art fails to teach a carrier comprising a matrix of inorganic, or organic, or organic and inorganic material and a biomolecular interaction entrapped within the matrix wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other.

The predictability or lack thereof in the art- in view of the lack of teachings in the prior art that shows or suggests a biomolecular interaction, entrapped within the matrix, wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other, the level of predictability is low. While it may be possible to reversibly dissociate the biological species of the biomolecular interaction by adding GdHCl or urea or subjecting the biomolecular interaction under thermal condition as described in the instant specification, it has not been shown that the biomolecular interaction can be reversibly dissociated by itself or by adding other compounds.

The amount of direction or guidance present – the instant specification provides guidance for reversibly dissociating the biomolecular interaction using only urea, GdHCl, or subjecting such biomolecular interaction to thermal condition- see example 3, page 32.

The absence of working examples – the examples disclosed in the specification only show reversibly dissociating the biomolecular interaction by adding urea, GdHCl or thermal condition.

The quantity of experimentation necessary – it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art- the level of skill in the art is high.

The breadth of the claims – the claimed carrier comprises a matrix of organic, inorganic, or organic and inorganic material and a biomolecular entrapped within the matrix wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from each other.

The instant specification describes that the biological species of the biomolecular interaction can be reversibly dissociated from each other only when a reversibly disrupting factor such as urea, GdHCl, or thermal is applied. Without such reversibly disrupting factor, the complex or biomolecular interaction would not be disrupted and thus reversibly dissociation would not take place. The instant specification fails to teach any other possible factor which would reversibly dissociate the biomolecular interaction or that the biomolecular interaction would reversibly dissociate on its own-without the

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aid of a disrupting factor. At best, the instant specification is enabled for a carrier comprising a matrix of organic, inorganic, organic and inorganic material, a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction can be reversibly dissociated from each other when adding urea, GdHCl, or thermal/heat, but the specification is not enabled for a biomolecular interaction that can reversibly dissociate on its own or by any other compounds. An undue amount of experimentation would be required to identify any possible reversibly dissociating compounds for reversibly dissociating the biomolecular interaction entrapped within the matrix of the carrier.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
October 21, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/6Y1